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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 08/996,768 | 12/23/97 | WENDEL A | P61750US0 |

| EXAMINER | |
|---|---|
| HINES, J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1641 | 17 |

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**DATE MAILED:** 01/04/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 08/996,768 | Wendel et al. |
| **Examiner** | **Group Art Unit** |
| Ja-Na Hines | 1641 |

☒ Responsive to communication(s) filed on *Oct 27, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *19-25 and 27-29* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *19-25 and 27-29* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

**Application Papers**

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

2. In view of the response filed on October 27, 1999, PROSECUTION IS HEREBY REOPENED. New Grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(a) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(b) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

3. The Examiner acknowledges amended claims 19-20, 25 and 27-29 and the cancellation of claim 26 filed on October 27, 1997. Claims 19-25 and 27-29 are pending in this Office Action.

### *Specification*

4. **Content f Specification**

(a) Title of the Invention: See 37 CFR 1.72(a). The title of the invention should be placed at the top of the first page of the specification. It should be brief but technically accurate and descriptive, preferably from two to seven words.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MEP. § 201.11.

© Statement Regarding Federally Sponsored Research and Development: See MEP. § 310.

(d) Reference to a "Microfiche Appendix": See 37CFR 1.96© and MEP. § 608.05. The total number of microfiche and the total number frames should be specified.

(e) Background of the Invention: The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(f) Brief Summary of the Invention: A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(g) Brief Description of the Several Views of the Drawing(s): A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(h) Detailed Description of the Invention: A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. This item may also be titled "Best Mode for Carrying Out the Invention." Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be

described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(I) Claim or Claims: See 37 CFR 1.75 and MEP. § 608.01(m). The claim or claims must commence on separate sheet. (37 CFR 1.52(b)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps.

(j) Abstract of the Disclosure: A brief narrative of the disclosure as a whole in a single paragraph of 250 words or less on a separate sheet following the claims.

(k) Drawings: See 37 CFR 1.81, 1.83-1.85, and MEP. § 608.02.

(l) Sequence Listing: See 37 CFR 1.821-1.825.

***Drawings***

5. The drawings are objected to for reasons set forth on NOTICE OF DRAFTSPERSON"S PATENT DRAWING REVIEW (PTO-948). Correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 19-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague because it is incomplete. The claims lacks a correlation step that relates the immunofunctional, toxic and/or modulatory reaction to the exposure to test materials.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 19-25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wendel et al. (EPA 741,294, DE Appl. 19, 516,247), in view of Boyse et al., (US Patent 5,004,681) Wendel et al., teaches a method for examining substances for pyrogenic activity. The whole blood containing preparations are brought into contact with the substances to be tested and then the preparations are examined for the formation of endogenous pyrogens. The preparations can contain coagulation inhibitors as well as diluents such as cell culture medium or physiological saline. Tests that measure the formation of the endogenous pyrogens include measurements of interleukin-1, interleukin-6, tumor necrosis factor, or $PGE_2$. However, Wendel et al., is silent to the use of frozen blood and cryopreservation.

Boyse et al., teaches the preservation of neonatal or fetal blood cells that have been cryopreserved and thawed can be used for autologous reconstitution. Freezing is destructive to most living cells however cryoprotective agents and optimal cooling rates can protect against cell injury (col. 6 lines 33-46). Various groups have looked at the effect of cooling velocity or cryopreservatives upon the survival or transplantation efficiency of frozen bone marrow cells or red blood cells (col. 6 lines 50-68) and the successful recovery of cells after long-term storage in liquid nitrogen has been described (col. 7 lines 1-17). The blood samples can be received with anticoagulants mixed therein (col. 18 lines 45-48). The inspection and testing of the blood can test for the presence of bacterial cultures (col. 17 lines 40-45) or diagnostic

screening for pathogenic microorganisms (col. 17 lines 46-60). Whole neonatal blood cryopreserved and thawed can be used for therapy (col. 24 lines 33-38).

Therefore, it would have been obvious to have used the frozen blood samples and cryopreservation of blood as taught by Boyse et al., in the method of Wendel et al., because frozen blood does not lose its ability to function and cryopreservation can be stored until use and this would provide an advantage in the method of Wendel et al.

8. Claims 19-25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wendel et al. (EPA 741,294, DE Appl. 19, 516,247), in view of Dinarello (US Patent 4,434,237) and in further view of Boyse et al., (US Patent 5,192,553). Wendel et al., has been discussed above, however, Wendel et al., is silent to the use of frozen blood and cryopreservation.

Dinarello teaches major advance in efforts to identify potentially pyrogenic pharmaceuticals or to identify particular lots of non-pyrogenic pharmaceuticals that are contaminated with trace amounts of highly active pyrogens (col. 3 lines 45-49). The invention consist of incubating the substance in the presence of the cell mixture and analyzing the results using well known methods (col. 3 lines 50-68). In order to prevent clotting of the blood cells, an anticoagulant such as citrate or heparin is preferred (col. 4 lines 42-46). Suitable diluents include isotonic solutions of salts or non-toxic compounds can be used (col. 4 lines 55-65). Analysis can be determined by methods such as radioimmunoassay, enzyme immunoassays and latex agglutination methods (col. 11-13 lines 35-17).

Boyse et al., (US Patent 5,192,553) teaches the preservation of neonatal or fetal blood cells that have been cryopreserved and thawed can be used for self reconstitution (abstract). Intracellular freezing and solution effects are responsible for cell injury (col. 6 lines 57-58). Cryoprotective agents and optimal

cooling rates can protect against cell injury (col. 6 lines 64-68). Cryoproctection by solute addition is thought to reduce the amount of ice formed and decrease the rate of flow out of the cell to protect the cell (col 6-7 lines 67-3). The blood samples can be received with anticoagulants mixed therein (col. 18 lines 45-48). The inspection and testing of the blood can test for the presence of bacterial cultures (col. 17 lines 40-45) or diagnostic screening for pathogenic microorganisms (col. 17 lines 46-60). Frozen cells can be thawed quickly (col. 24 lines 53-61). Also, it is envisioned that whole neonatal blood, which has been cryopreserved and thawed can be used (col. 24 lines 64-68).

Therefore, it would have been obvious to have used the frozen whole blood samples and cryopreservation techniques of blood as taught by Boyse et al., (US Patent 5,192,553), in the method of Wendel et al., and Dinarello because frozen blood is protected against cellular injury and can be stored and this would provide an advantage in the method of Wendel et al., and Dinarello.

***Response to Arguments***

9. Claim 20 is indefinite. The term "immune-related data" is unclear. The metes and bounds of the term are indefinite is withdrawn.

10. Claim 21-26 are indefinite. Claim 21 recites the limitation "the group" in the claim. There is insufficient antecedent basis for this limitation in the claim is withdrawn.

11. Claims 21-24 are rejected under 35 U.S.C. 102(a) as being anticipated by Sobota et al., is withdrawn in view of applicants' section 119 priority date.

12. Claims 19-20 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wendel et al. (EPA 741,294, DE Appl. 19, 516,247), in view of Sobota et al., is withdrawn in view of applicants' section 119 priority date.

***Prior Art***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Allsopp et al., teaches different responses on the cryopreservation of peripheral blood. Busch et al., teaches the evaluation of screened blood donations. Durrant et al., teaches the use of cryopreserved PBLs. Martin et al., teaches cytokine and bioassays. Venkataraman teaches cryopreserved-induced enhancement of interleukin-2 production in human peripheral blood.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

January 3, 1999

James C. Housel 1/3/00

JAMES C. HOUSEL
SUPERVISORY PATENT EXAMINER